REMARKS

Claims 22-40 were pending. New claims 41-44 have been added, and thus claims 22-44 will be pending upon entry of the instant amendment.

Claims 23-24 and 26-27 are objected to because they recite improper Markush groups. Claims 22, 25, 28 and 32 are rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite; claims 22, 23, 25, 26, 28-32 and 35-40 are rejected under 35 U.S.C. §112, first and second paragraphs, for allegedly lacking written description and enablement. In order to place the claims in condition for allowance, Applicants have amended claims 22-40. Support for the amendments can be found, for example, at page 7, line 36, to page 8, line 7, and in Examples 4.1 and 4.2 of the instant specification. As such, no new matter has been added by these amendments.

For reasons set forth in detail below, Applicants request that the objections and rejections be withdrawn and all claims be allowed.

The Claim Objections

Claims 23-24 and 26-27 are objected to because they recite improper Markush groups. Applicants have amended each claim, as suggested by the Examiner, to correct the form of the claim, thereby overcoming the objection. As such, Applicants respectfully request that the objection of claims 23-24 and 26-27 be withdrawn.

The Claims are Definite as Required by 35 U.S.C. §112, Second Paragraph

Claims 22, 25, 28 and 32 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants have amended each claim, as suggested by the Examiner, to clarify the meaning of "utilizing" in claims 22 and 25 and "hydrolyzing" in claims 28 and 32, thereby obviating the rejection. As such, Applicants respectfully request that the rejection of claims 22, 25, 28 and 32 under 35 U.S.C. §112, first paragraph, be withdrawn.

The Claimed Subject Matter is Adequately Described as Required by 35 U.S.C. §112, First Paragraph

Claims 22, 23, 25, 26, 28-32 and 35-40 stand rejected under 35 U.S.C. §112, first paragraph, allegedly for "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." (March 4, 2002 Office Action at page 5).

Claim 28 has been amended without prejudice to Applicants' right to pursue the canceled subject matter in subsequent applications. Specifically, Applicants have removed reference in claim 28 to use of polypeptides with amidohydrolase activity which can hydrolyze THMP. Accordingly, the rejection of claim 28 with respect to the alleged lack of written description of such polypeptides has been obviated.

Despite acknowledging that the claims are directed to microorganisms that are characterized by utilization of THMP as the sole source of nitrogen, the Examiner has summarily concluded that the scope of the claimed microorganisms constitutes an extremely large and variable genus. Further, the Examiner maintains the rejection under 35 U.S.C. §112, first paragraph, because the specification allegedly does not contain any other characteristic feature of the claimed microorganisms apart from their ability to use THMP as the only nitrogen source.

Applicants maintain that the specification does indeed describe the claimed microorganisms in such a way as to indicate possession of the invention at the time of filing the application. In particular, the instant specification (*e.g.*, at page 1, lines 1-14) defines the claimed microorganisms as only those that utilize propionamide of the formula VI in the form of the racemate or of its optically active isomers as the sole nitrogen source. Indeed, the instant specification teaches the identification and isolation of eight different microorganisms in the genus *Rhodococcus, Arthrobacter, Bacillus, Klebsiella* or *Pseudomonas* that utilize (R)-3,3,3-trifluoro-2-hydroxy-2-methylpropionamide ("THMP") as their only nitrogen source.

Further, Applicants have amended independent claims 22 and 25 to recite that the genus is able to hydrolyze the propionate, which more particularly points out the subject matter which Applicants regard as the invention. As such, Applicants submit that the claimed genus encompasses a reasonable number of species, and that the instant specification adequately describes the full scope of the claims as required by 35 U.S.C. §112, first paragraph. Accordingly, Applicants respectfully request that the rejection of claims 22, 23, 25, 26, 28-32 and 35-40 under 35 U.S.C. §112, first paragraph, be withdrawn.

The Claims are Enabled in Accordance with 35 U.S.C. §112, First Paragraph

Claims 22, 23, 25, 26, 28-32 and 35-40 stand rejected under 35 U.S.C. §112, first paragraph, allegedly for lack of enablement. The Examiner concedes that the specification is enabling for isolated microorganisms that can utilize THMP as its sole source of nitrogen, such as *K.oxytoca* PRS1, *K.Oxytoca* PRS1K17, *R. opacus* ID-622, *A.ramosus* ID620, *Bacillus sp.* ID-621, *K.planticula* ID-624, *K.pneumoniae* ID-625 or *Pseudomonas sp.* (DSM 11355). However, the Examiner contends that the instant specification "does not reasonably provide enablement for claiming any or all microorganisms (including variants and mutants) or any other strain or species or culture of the above microorganisms with the characteristic property of utilizing THMP as [the] sole nitrogen source." Thus, the Examiner summarily concludes that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claimed subject matter (March 4, 2002 Office Action at pages 3-4). For the reasons discussed below, Applicants respectfully assert that the instant specification as originally filed is fully enabling.

The enablement requirement refers to the requirement of 35 U.S.C. §112, first paragraph, that the information contained in the specification be sufficient to inform those skilled in the relevant art how to make and use the claimed invention. Therefore, the required showing is merely to explain how to make and use the invention as defined by the claims.

The standard for determining whether the specification meets the enablement requirement is whether the experimentation needed to practice the invention is undue or

unreasonable. *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916). Accordingly, even though 35 U.S.C. §112 does not recite the phrase "undue experimentation," the statute has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement). *See also United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.").

"A patent's disclosure is adequate if it defines the desired functional relationship, even if some experimentation is required to reproduce the invention." *Wilden Pump & Eng'r Co. v. Pressed & Welded Prod. Co.*, 199 U.S.P.Q. 390 (N.D. Cal. 1978), *aff'd*, 655 F.2d 984, 213 U.S.P.Q. 282 (9th Cir. 1981), *on remand*, 570 F. Supp. 224, 224 U.S.P.Q. 1074 (N.D. Cal. 1983). Thus, the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 219 (CCPA 1976); *In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404. Undue experimentation has been defined by the courts as experimentation that would require a level of ingenuity beyond what is expected from one of ordinary skill in the field. *See, e.g., Fields v. Conover*, 170 U.S.P.Q. 276, 279 (C.C.P.A.1971).

Many factors are to be considered when determining whether there is sufficient disclosure to satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include the (a) breadth of the claims; (b) nature of the invention; (c) state of the prior art; (d) level of one of ordinary skill; (e) level of predictability in the art; (f) amount of direction provided by the inventor; (g) existence of working examples; and (h) quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404. Accordingly, a determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above factual considerations. *In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404. It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. Thus, the Examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. *In re Wands*, 858 F.2d at 740, 8 U.S.P.Q.2d at 1407. In addition, the Examiner should specifically identify what information is missing in alleging lack of enablement and why one skilled in the art could not supply the information without undue experimentation. *See* M.P.E.P. §2164.06(a).

Holding that the specification was enabling with respect to the claims at issue, the *Wands* court noted that there was no disagreement as to the facts, but merely a disagreement as to the interpretation of the data and the conclusion to be made from the facts. The court found "considerable direction and guidance [in the specification,] a high level of skill in the art at the

time the application was filed, [and that] all of the methods needed to practice the invention were well known" and concluded that "it would not require undue experimentation to practice the claimed invention." *In re Wands*, 858 F.2d at 740, 8 U.S.P.Q.2d at 1406-7.

This is the case here. As long as the specification discloses at least one method for making and using the claimed invention that bears a "reasonable correlation" to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (CCPA 1970); *see also* M.P.E.P. §2164.01(b). Applicants respectfully assert that the instant specification, in combination with standard techniques well known in the prior art, teaches how to make and use the claimed invention. Specifically, Examples 4.1 and 4.2, which describe a procedure for isolating microorganisms of the invention by first selecting microorganisms that use propionamide of the formula VI and further selecting those that hydrolyze the propionamide, fully describe by working examples how to make and use the claimed invention. Moreover, all required assays to practice the invention are merely routine and known in art.

The Examiner claims that the instant specification describes but a small genus of microorganisms that utilize THMP as its sole source of nitrogen. Applicants have amended independent claims 22 and 25 to more particularly define the genus as capable of hydrolyzing the propionamide, and have described the identification and isolation of eight representative species. For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art would expect that the claimed genus could be used in that manner without undue experimentation. Proof of enablement for

other members of the claimed genus is required only where adequate reasons are advanced by the Examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation. *See* M.P.E.P. §2164.03. Additionally, the presence of few working examples cannot be the sole reason for rejecting claims as being broader than the enabling disclosure. *See* M.P.E.P. §2164.02. Thus, to make a valid rejection, the Examiner must evaluate all the facts and evidence and state why the skilled artisan would not expect to be able to extrapolate the working examples using the disclosed species across the entire scope of the claims.

The Examiner's conclusion of non-enablement was not accompanied by an analysis of the factual considerations outlined in *Wands*. Rather , the Examiner simply contends that "the specification does not support the broad scope of the claims . . . because the specification does not establish: (A) that the mechanism involved (enzymatic pathway) in the use of THMP as [the] sole source of nitrogen is universal in all microorganisms and; (B) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful" (March 4, 2002 Office Action at pages 4-5).

Applicants respectfully submit that a detailed description of the enzymatic pathway implicated in the use of THMP as source of nitrogen and demonstration of its universality in all microorganisms is not required to enable the breadth of the claims. The instant specification adequately defines the desired functional relationship (*i.e.*, ability to use THMP as its only nitrogen source and to hydrolyze the propionamide. Additionally, any experimentation required to practice the claimed invention cannot be said to require a level of ingenuity beyond

that of the skilled artisan. In fact, the specification teaches, by working examples, a method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claims.

Moreover, contrary to the Examiner's position that "the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful" (Office Action at pages 4-5), the isolation of eight microorganisms that use THMP and hydrolyze propionamide (*see, e.g.*, the instant specification at page 2, line 34 through page 3, line 30 and Example 4) (1) demonstrates that, following the precise teachings of the specification, microorganisms that use THMP as a sole source of nitrogen and hydrolyze the propionamide can be identified; (2) provides proof of principle that any experimentation is not undue and has a reasonable likelihood of success for identifying claimed microorganisms; and (3) proves that, despite any necessary experimentation, the skilled artisan is given adequate guidance to practice the claimed invention. *In re Colianni*, 561 F.2d 220, 224, 195 U.S.P.Q. 150, 153 (CCPA 1977) ("[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance.").

The Examiner further contends that "experimentation to identify . . . microorganisms from a group consisting [of] hundreds and thousands of microorganisms would constitute undue burden to one skilled in the art" (March 4, 2002 Office Action at page 4). Enablement is not precluded even if some experimentation is necessary. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947. This is so even if the amount of experimentation required is considerable and laborious. *In re*

Wands, 858 F.2d at 731. In *Hybritech*, screening of hundreds of cells to find a single cell having the desired biological activity was deemed to be an acceptable amount of experimentation. Following the instant specification's teachings, much less experimentation was required to identify numerous microorganisms that use THMP and hydrolyze propionamide, such that the amount of experimentation necessary to make and use the presently claimed invention would clearly be deemed acceptable under *Hybritech*. As discussed above, the specification provides extensive guidance regarding the required steps for identifying the microorganisms of the invention. Moreover, the routine nature of the disclosed microbiological assays, which provides for simple and quick determinations of a microorganism's growth capability in the presence of THMP and its hydrolase activity towards propionamide, undercuts the Examiner's concerns regarding undue experimentation.

Finally, with respect to the enablement requirement and claim scope, it is well settled that the inclusion of undisclosed species within a broad genus does not necessarily render a claim unduly broad. *Horton v. Stevens*, 7 U.S.P.Q.2d 1245, 1247 (Bd. Pat. App. & Int'f. 1988) ("The mere fact that a claim embraces undisclosed or inoperative species or embodiments does not necessarily render it unduly broad."). *Precision Metal Fabricators Inc. v. Jetstream Systems Co.*, 6 U.S.P.Q.2d 1704, 1709 (N.D. Cal. 1988) ("The enablement requirement does not require that the patent disclose the specific embodiment of the claim; a broad claim can be enabled by the disclosure of a single embodiment."). Also, disclosure of every operable species in a genus is not required to claim the genus, even in unpredictable arts. *See* M.P.E.P. §2164.03. As discussed above, Applicants have disclosed eight different microorganisms and precisely taught

methods of identifying and isolating such microorganisms. Thus, based on the weight of all the evidence detailed above, Applicants respectfully submit that the specification fully enables, within the meaning of 35 U.S.C. §112, the claimed genus.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

CONCLUSION

Entry of the foregoing remarks into the file history of the above-identified application is respectfully requested. Applicants believe that the foregoing amendments and remarks place the claims in condition for allowance, and thus respectfully request reconsideration of the pending claims and withdrawal of the outstanding rejections. An allowance is earnestly sought.

Respectfully submitted,

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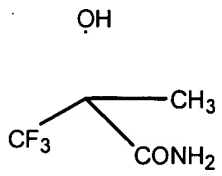
Date: July 3, 2002

Enclosures

EXHIBIT A
MARKED-UP VERSION OF AMENDED CLAIMS IN APPLICATION NO. 09/214,679

22. (Amended) A biologically pure culture of a microorganism [capable of utilizing]

wherein said microorganism utilizes propionamide of the formula:



VI

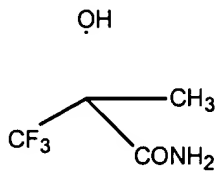
in the form of the racemate or of its optically active isomers as the sole nitrogen source; and wherein said microorganism hydrolyzes said propionamide.

23. (Amended) The microorganism of claim 22 wherein said microorganism is selected from the group consisting of the genus *Rhodococcus, Arthrobacter, Bacillus, Klebsiella* [or] and *Pseudomonas*.

24. (Amended) The microorganism of claim 23 wherein [the] said microorganism is selected from the group consisting of the species *Klebsiella oxytoca PRS1 (DSM 11009), Klebsiella oxytoca PRS1K17 (DSM 11623), Rhodococcus opacus ID-662 (DSM 11344), Arthrobacter ramosus ID-620 (DSM 11350), Bacillus sp. ID-621 (DSM 11351), Klebsiella planticula ID-624 (DSM 11354), Klebsiella pneumoniae ID-625 (DSM 11355)* [or of the species] and *Pseudomonas sp. (DSM 11010)*.

25. (Amended) A cell extract derived from a biologically pure culture of a microorganism [capable of utilizing]

wherein said microorganism utilizes propionamide of the formula:



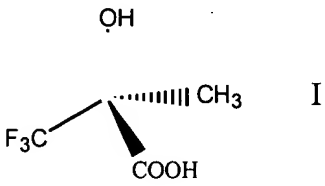
VI

in the form of the racemate or of its optically active isomers as the sole nitrogen source; and wherein said microorganism hydrolyzes said propionamide.

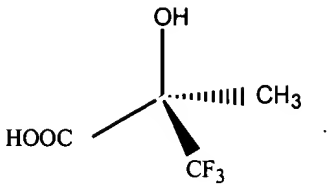
26. (Amended) The cell extract of claim 25 wherein said microorganism is selected from the group consisting of the genus *Rhodococcus, Arthrobacter, Bacillus, Klebsiella* [or] and *Pseudomonas*.

27. (Amended) The cell extract of claim 26 wherein [the] said microorganism is selected from the group consisting of the species *Klebsiella oxytoca PRS1* (DSM 11009), *Klebsiella oxytoca PRS1K17* (DSM 11623), *Rhodococcus opacus ID-662* (DSM 11344), *Arthrobacter ramosus ID-620* (DSM 11350), *Bacillus sp. ID-621* (DSM 11351), *Klebsiella planticula ID-624* (DSM 11354), *Klebsiella pneumoniae ID-625* (DSM 11355) [or of the species] and *Pseudomonas sp.* (DSM 11010).

28. (Amended) A process for the preparation of (S) - or (R) -3, 3, 3-trifluoro-2-hydroxy-2-methylpropionic acid of the formula:

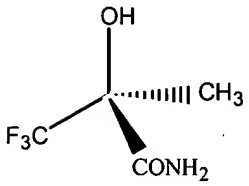


I

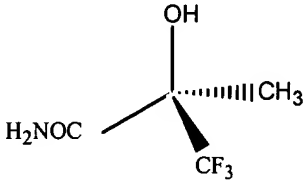


II

[and/or] or of (R) - or (S) -3, 3, 3-trifluoro-2-hydroxy-2-methylpropionamide of the formula

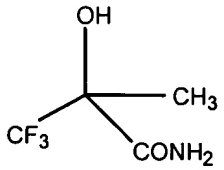


VII



VIII

comprising [the conversion of] converting propionamide of the formula



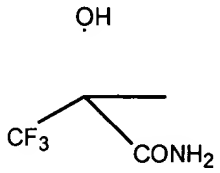
VI

into [the compounds of the formulae] a compound of the formula I, II, VII or VIII using:

(a) the microorganism of claim 22, 23 [or], 24 , 40 or 41; or

(b) the cell [extracts] extract of claim 25, 26 [or], 27 , 42 or 43 [; or

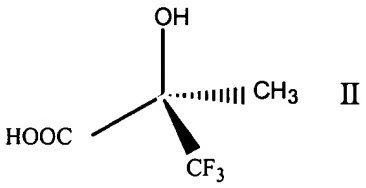
(c) a polypeptide having amidohydrolase activity capable of hydrolysing (R)-3, 3, 3-tri fluro-2-hydroxy-2-methylpropionamide of the formula



VI] .

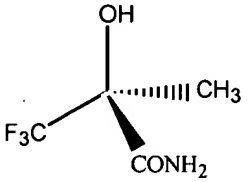
29. (Amended) The process of claim 28 further comprising the step of isolating [the compounds] a compound of the formula I, II, VII or VIII.

30. (Amended) A process for the preparation of (R) -3, 3, 3-trifluoro-2-hydroxy-2-methylpropionic acid of the formula



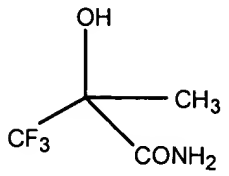
II

[and/or] or of (S) -3, 3, 3-trifluoro-2-hydroxy-2-methyl-propionamide of the formula



VII

comprising [the conversion of] converting propionamide of the formula

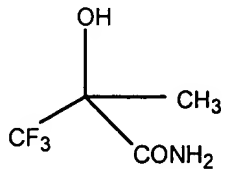


VI

into the compound of the formula II utilizing the microorganism of claim 22, 23, 24, 41 or 42.

31. (Amended) The process of claim 30 further comprising the step of isolating the compound of formula II [and/or of the compound of] or formula VII.

32. (Amended) The process of claim 30 wherein [the] said microorganism contains a nucleic acid molecule encoding a polypeptide having aminohydrolase activity [capable of hydrolyzing] wherein said polypeptide hydrolyzes (R) -3, 3, 3-trifluoro-2-hydroxy-2-methylpropionamide of the formula:



VI

33. (Amended) The process of claim 32 wherein [the] said nucleic acid molecule encodes the amino acid sequence of SEQ ID [No. 2] NO:2.

34. (Amended) The process of claim 32 wherein [the] said nucleic acid molecule is selected from the group consisting of:

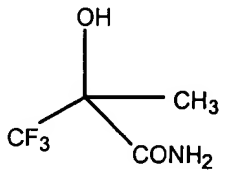
(a) a nucleic acid molecule comprising the sequence of SEQ ID [No. 1] NO:1;

(b) a nucleic acid molecule comprising the sequence complementary to SEQ ID NO:1; [sequences which are complementary thereto; and

(b)] and (c) [DNA sequences] a nucleic acid molecule which [hybridize] hybridizes under stringent hybridization conditions to SEQ ID [No. 1] NO:1; wherein said nucleic acid molecule encodes [and which encode] a polypeptide with stereospecific amidohydrolase activity.

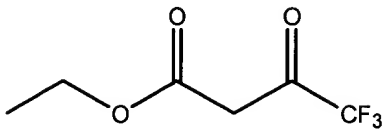
35. (Amended) The process of claim 30 wherein [the] said microorganism is of the genus *Klebsiella*.

36. (Amended) The process of claim 28 or 30 characterized in that the propionamide of the formula



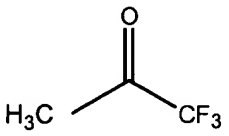
VI

is prepared by converting, in a first step, trifluoroacetate of the formula



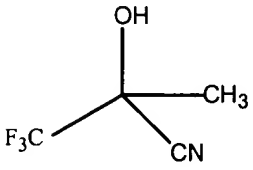
III

into trifluoroacetone of the formula



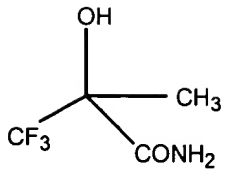
IV

using a mineral acid, converting the former, in the second step, into the propionitrile of the formula



V

using a cyanide, and converting the former, in the third step, into the propionamide of the formula



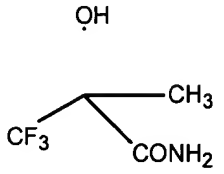
VI

(a) chemically using concentrated mineral acid; or (b) [microbiologically] biologically using [mutated] microorganisms of the genus *Rhodococcus*.

37. (Amended) The process of claim 36 wherein [the] said mineral acid is selected from the group consisting of: sulphuric acid, phosphoric acid [or] and nitric acid.

38. (Amended) The process of claim 36 wherein [the] said cyanide is an alkali metal cyanide.

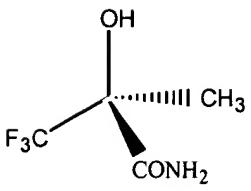
39. (Amended) The process of claims 28, 30, or 36 characterized in that the conversion of the propionamide of the formula



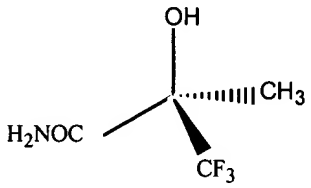
VI

is carried out using microorganisms of the genus selected from the group consisting of *Klebsiella, Rhodococcus, Arthrobacter, Bacillus, Escherichia, Comamonas, Acinetobcter, Rhizobium, Agrobacterium, Rhizobium/Agrobacterium* [or] and *Pseudomonas.*

40. (Amended) The process of claims 28 or 30, characterized in that the (S) - or (R) -3, 3, 3-trifluoro-2-hydroxy-2-methylpropionamide of the formula



VII



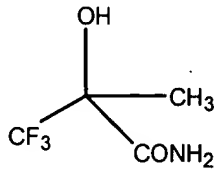
VIII

is hydrolysed to the compound of the formula I or II [, either] (a) chemically in the presence of a base or (b) biologically [microbiologically] using microorganisms of the genus *Rhodococcus.*

EXHIBIT B
PENDING CLAIMS IN U.S. APPLICATION NO. 09/214,679
UPON ENTRY OF JULY 3, 2002 AMENDMENT

22. A biologically pure culture of a microorganism

wherein said microorganism utilizes propionamide of the formula:



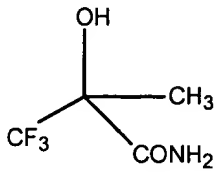
VI

in the form of the racemate or of its optically active isomers as the sole nitrogen source; and wherein said microorganism hydrolyzes said propionamide.

23. The microorganism of claim 22 wherein said microorganism is selected from the group consisting of the genus *Rhodococcus, Arthrobacter, Bacillus, Klebsiella* and *Pseudomonas*.

24. The microorganism of claim 23 wherein said microorganism is selected from the group consisting of the species *Klebsiella oxytoca PRS1 (DSM 11009), Klebsiella oxytoca PRS1K17 (DSM 11623), Rhodococcus opacus ID-662 (DSM 11344), Arthrobacter ramosus ID-620 (DSM 11350), Bacillus sp. ID-621 (DSM 11351), Klebsiella planticula ID-624 (DSM 11354), Klebsiella pneumoniae ID-625 (DSM 11355)* and *Pseudomonas sp. (DSM 11010)*.

25. A cell extract derived from a biologically pure culture of a microorganism wherein said microorganism utilizes propionamide of the formula:



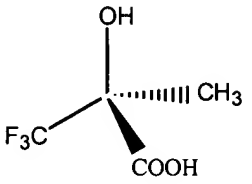
VI

in the form of the racemate or of its optically active isomers as the sole nitrogen source; and wherein said microorganism hydrolyzes said propionamide.

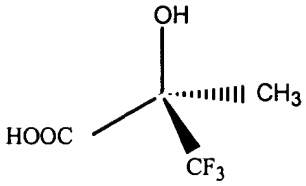
26. The cell extract of claim 25 wherein said microorganism is selected from the group consisting of the genus *Rhodococcus, Arthrobacter, Bacillus, Klebsiella* and *Pseudomonas*.

27. The cell extract of claim 26 wherein said microorganism is selected from the group consisting of the species *Klebsiella oxytoca PRS1* (DSM 11009), *Klebsiella oxytoca PRS1K17* (DSM 11623), *Rhodococcus opacus ID-662* (DSM 11344), *Arthrobacter ramosus ID-620* (DSM 11350), *Bacillus sp. ID-621* (DSM 11351), *Klebsiella planticula ID-624* (DSM 11354), *Klebsiella pneumoniae ID-625* (DSM 11355) and *Pseudomonas sp.* (DSM 11010).

28. A process for the preparation of (S) - or (R) -3, 3, 3-trifluoro-2-hydroxy-2-methylpropionic acid of the formula:

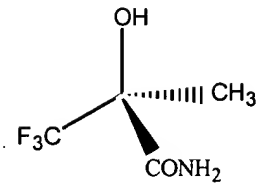


I

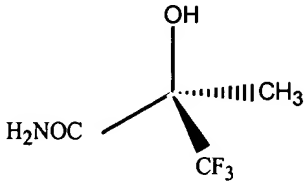


II

or of (R) - or (S) -3, 3, 3-trifluoro-2-hydroxy-2-methylpropionamide of the formula

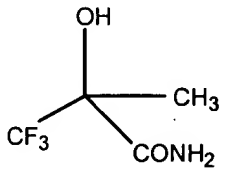


VII



VIII

comprising converting propionamide of the formula



VI

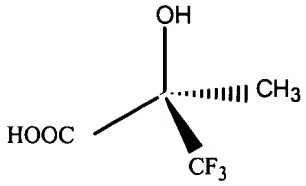
into a compound of the formula I, II, VII or VIII using:

(a) the microorganism of claim 22, 23, 24, 40 or 41; or

(b) the cell extract of claim 25, 26, 27, 42 or 43.

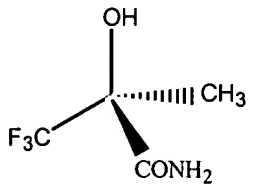
29. The process of claim 28 further comprising the step of isolating a compound of the formula I, II, VII or VIII.

30. A process for the preparation of (R) -3, 3, 3-trifluoro-2-hydroxy-2-methylpropionic acid of the formula



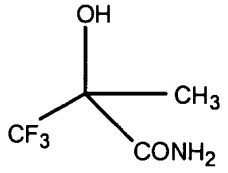
II

or of (S) -3, 3, 3-trifluoro-2-hydroxy-2-methyl-propionamide of the formula



VII

comprising converting propionamide of the formula

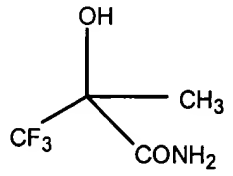


VI

into the compound of the formula II utilizing the microorganism of claim 22, 23, 24, 41 or 42.

31. The process of claim 30 further comprising the step of isolating the compound of formula II or formula VII.

32. The process of claim 30 wherein said microorganism contains a nucleic acid molecule encoding a polypeptide having aminohydrolase activity wherein said polypeptide hydrolyzes (R) -3, 3, 3-trifluoro-2-hydroxy-2-methylpropionamide of the formula:



VI

33. The process of claim 32 wherein said nucleic acid molecule encodes the amino acid sequence of SEQ ID NO:2.

34. The process of claim 32 wherein said nucleic acid molecule is selected from the group consisting of:

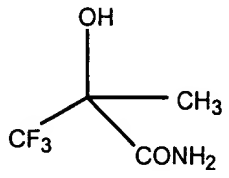
(a) a nucleic acid molecule comprising the sequence of SEQ ID NO:1;

(b) a nucleic acid molecule comprising the sequence complementary to SEQ ID NO:1; and

(c) a nucleic acid molecule which hybridizes under stringent hybridization conditions to SEQ ID NO:1; wherein said nucleic acid molecule encodes a polypeptide with stereospecific amidohydrolase activity.

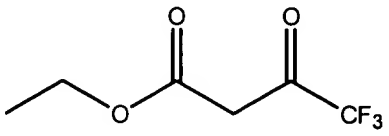
35. The process of claim 30 wherein said microorganism is of the genus *Klebsiella*.

36. The process of claim 28 or 30 characterized in that the propionamide of the formula



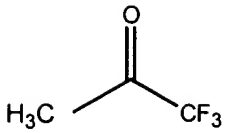
VI

is prepared by converting, in a first step, trifluoroacetate of the formula



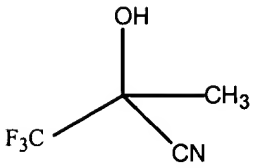
III

into trifluoroacetone of the formula



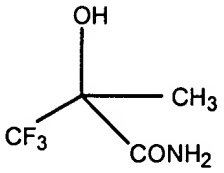
IV

using a mineral acid, converting the former, in the second step, into the propionitrile of the formula



V

using a cyanide, and converting the former, in the third step, into the propionamide of the formula



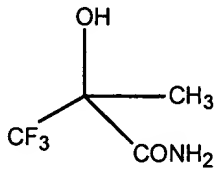
VI

(a) chemically using concentrated mineral acid; or (b) biologically using microorganisms of the genus *Rhodococcus*.

37. The process of claim 36 wherein said mineral acid is selected from the group consisting of: sulphuric acid, phosphoric acid and nitric acid.

38. The process of claim 36 wherein said cyanide is an alkali metal cyanide.

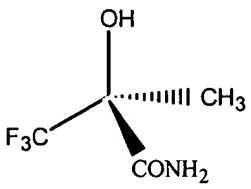
39. The process of claims 28, 30, or 36 characterized in that the conversion of the propionamide of the formula



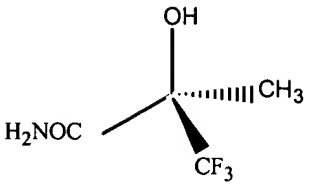
VI

is carried out using microorganisms of the genus selected from the group consisting of *Klebsiella, Rhodococcus, Arthrobacter, Bacillus, Escherichia, Comamonas, Acinetobcter, Rhizobium, Agrobacterium, Rhizobium/Agrobacterium* and *Pseudomonas.*

40. The process of claims 28 or 30, characterized in that the (S) - or (R) -3, 3, 3-trifluoro-2-hydroxy-2-methylpropionamide of the formula



VII

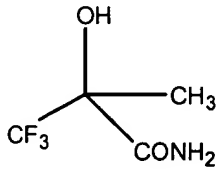


VIII

is hydrolysed to the compound of the formula I or II (a) chemically in the presence of a base or (b) biologically using microorganisms of the genus *Rhodococcus*.

41. A biologically pure culture of a microorganism

wherein said microorganism utilizes propionamide of the formula:

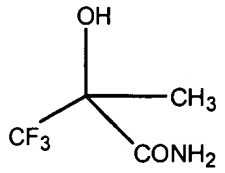


VI

in the form of the racemate or of its optically active isomers as the sole nitrogen source; and wherein said microorganism is selected from the group consisting of the *genus Rhodococcus, Arthrobacter, Bacillus, Klebsiella* and *Pseudomonas*.

42. A biologically pure culture of a microorganism

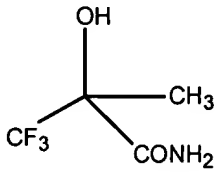
wherein said microorganism utilizes propionamide of the formula:



VI

in the form of the racemate or of its optically active isomers as the sole nitrogen source; and wherein said microorganism is selected from the group consisting of the species *Klebsiella oxytoca PRS1 (DSM 11009), Klebsiella oxytoca PRS1K17 (DSM 11623), Rhodococcus opacus ID-662 (DSM 11344), Arthrobacter ramosus ID-620 (DSM 11350), Bacillus sp. ID-621 (DSM 11351), Klebsiella planticula ID-624 (DSM 11354), Klebsiella pneumoniae ID-625 (DSM 11355)* and *Pseudomonas sp. (DSM 11010)*.

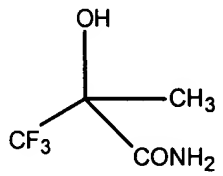
43. A cell extract derived from a biologically pure culture of a microorganism wherein said microorganism utilizes propionamide of the formula:



VI

in the form of the racemate or of its optically active isomers as the sole nitrogen source; and wherein said microorganism is selected from the group consisting of the genus *Rhodococcus, Arthrobacter, Bacillus, Klebsiella* and *Pseudomonas*.

44. A cell extract derived from a biologically pure culture of a microorganism wherein said microorganism utilizes propionamide of the formula:



VI

in the form of the racemate or of its optically active isomers as the sole nitrogen source; and wherein said microorganism is selected from the group consisting of the species *Klebsiella oxytoca PRS1* (DSM 11009), *Klebsiella oxytoca PRS1K17* (DSM 11623), *Rhodococcus opacus ID-662* (DSM 11344), *Arthrobacter ramosus ID-620* (DSM 11350), *Bacillus sp. ID-621* (DSM 11351), *Klebsiella planticula ID-624* (DSM 11354), *Klebsiella pneumoniae ID-625* (DSM 11355) and *Pseudomonas sp.* (DSM 11010).